

II. AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions, and listings, of the claims in the application.

Listing of the Claims

1. (Currently amended) A solid, oral controlled-release dosage form comprising an opioid agonist selected from the group consisting of oxycodone, morphine, hydromorphone, hydrocodone, pharmaceutically acceptable salts thereof and mixtures thereof; an opioid antagonist selected from the group consisting of naloxone, naltrexone, pharmaceutically acceptable salts thereof and mixtures thereof; and a controlled release material; the opioid agonist and the opioid antagonist released from the oral dosage form at substantially proportionate rates, and the amount of the opioid antagonist administered from the dosage form being from about 100 to about 1000 fold less than the amount of the opioid agonist; the opioid agonist and the antagonist contained in (i) a plurality of substrates selected from the group consisting of granules, pellets, beads, spheroids and granulates, wherein the substrates are coated with a coating comprising the controlled-release material or (ii) a matrix comprising the controlled release material, said the dosage form releasing during a dosing interval an analgesic or sub-analgesic amount of the opioid agonist along with an amount of ~~said the~~ the opioid antagonist effective to (i) attenuate a side effect of ~~said the~~ the opioid agonist selected from the group consisting of anti-analgesia, hyperalgesia, hyperexcitability, physical dependence, tolerance, and a combination of any of the foregoing, and to (ii) enhance the analgesic potency of the opioid agonist, the dosage form providing controlled-release of the opioid agonist and opioid antagonist over about a 12 hour period ~~said dosage form providing analgesia for at least about 8 hours when administered to human patients.~~

2-8. (Cancelled)

9. (Currently amended) The controlled-release dosage form of claim 1 5, wherein the opioid agonist and the antagonist are contained in a plurality of substrates coated with a coating comprising said controlled-release material, ~~said substrates being selected from the group consisting of granules, pellets, beads and spheroids.~~

10. (Currently amended) The controlled-release oral dosage form of claim 1, wherein the opioid antagonist is treated to modify its release rate before it is combined with the opioid agonist, ~~such that when the opioid agonist and the treated antagonist are combined into the controlled-release dosage form, the opioid agonist and antagonist are released from the dosage form at substantially proportionate rates.~~

11. (Currently amended) The controlled-release dosage form of claim 1, wherein ~~the dosage form is orally administered and~~ said opioid antagonist is treated to modify its release rate before it is combined with the opioid agonist, such that when the opioid agonist and the treated antagonist are combined into the controlled-release dosage form, the dosage form releases the agonist and the antagonist at such rate that the opioid agonist and the opioid antagonist are therapeutically effective over the dosing interval.

12. (Original) The controlled-release dosage form of claim 1, wherein the opioid antagonist is present as granulates comprising the opioid antagonist dispersed in a first controlled release matrix, and wherein the opioid agonist is present as granulates comprising the opioid agonist dispersed in a second controlled-release matrix, the first controlled-release matrix providing controlled-release of the opioid antagonist and the second matrix providing controlled-release of the opioid agonist.

13-19. (Cancelled)

20. (Original) The controlled-release dosage form of claim 1, wherein the dosage form

provides controlled-release of the opioid agonist and opioid antagonist over about a 24 hour period.

21-39 (Cancelled)

40. (New) The dosage form of claim 1, wherein the opioid agonist is oxycodone or a pharmaceutically acceptable salt thereof.

41. (New) The dosage form of claim 1, wherein the opioid agonist is morphine or a pharmaceutically acceptable salt thereof.

42. (New) The dosage form of claim 1, wherein the opioid agonist is hydromorphone or a pharmaceutically acceptable salt thereof.

43. (New) The dosage form of claim 1, wherein the opioid agonist is hydrocodone or a pharmaceutically acceptable salt thereof.

44. (New) The dosage form of claim 1, wherein the opioid antagonist is naloxone or a pharmaceutically acceptable salt thereof.

45. (New) The dosage form of claim 1, wherein the opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.